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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,724	01/22/2002	Peter H. Seeberger	MTV-037.01	3517

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623 //

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,724

Applicant(s)

SEEBERGER ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-9 and 18-22 is/are allowed.
- 6) ☒ Claim(s) 1-4, 10-12, 16, 17 and 23-26 is/are rejected.
- 7) ☒ Claim(s) 5 and 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Amendment filed April 14, 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1, 6, 11 and 15-17 have been amended.
2. Claims 13 and 14 have been cancelled without prejudice.
3. New Claims 23-26 have been added.
4. Remarks drawn to 35 U.S.C. 112 and 102(b) rejections.

Claims 1-12 and 15-26 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The rejection of claim 1 under 112 second paragraph has been overcome by applicants' amendment to the claim.

A new 112 second paragraph rejection is being advanced.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10, which depends from claim 6, recites a trisaccharide selected from the group consisting of two trisaccharides. The type of trisaccharide represented by the one at the bottom of claim 10 is not seen in claim 6 as amended. It is not clear if only the

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trisaccharide of the type shown at the top of claim 10 is claimed. This renders claim 10 indefinite.

Claim Rejections - 35 USC § 102

Claims 23-26 rejected as being unpatentable over Jaurand et al (Bioorganic & Medicinal Chemistry Letters, 1992, 2(9), 897-900) is being maintained.

The structure in Claim 23 as amended shows the middle saccharide bearing an OR" on carbon-2, wherein R" represents alkyl.

Structure 15 of Jaurand still anticipates the compound of claim 23. Structure 15 of Jaurand has a C₆H₅CH₂O- group on carbon-2 of the middle saccharide unit. This still reads on alkyl for R" of the instant structure. Jaurand's structure 15 is also seen to meet the limitations of Claims 24-26.

The rejection of Claims 1-4 as being unpatentable over Tamura, J. in Trends in Glycoscience and Glycotechnology, January 2001, 13(69), 65-68 is withdrawn. Claims 1-4 are rejected as being unpatentable over new art as contained herein below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamura et al (Liebig's Ann. 1996, 1239-1257).

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Tamura et al disclose a disaccharide (structure 16 α , page 1243) wherein the anomeric carbon has a OC(NH)CCl₃, R and R' are alkyl. This disclosure is seen to meet the limitations of Claims 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khane et al in combination with Kovensky et al (Bioorganic and Medicinal Chemistry 1999, 7, 1567-1580).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

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made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 12, 16 and 17 are drawn to a method of preparing a glycosaminoglycan comprising reacting a mono-, di- or trisaccharide comprising an activated anomeric carbon with a second mono- or di- or trisaccharide comprising a hydroxyl or amino group to form an oligosaccharide linked to a solid support, comprising a glycosidic linkage, wherein the first or the second mono- or di- or tri-saccharide is covalently linked to the support; sulfating the hydroxyl or amino moiety of the said oligosaccharide linked to the solid support and removing the hydroxyl or amino protecting group from the said oligosaccharide linked to the solid support by hydrogenolysis.

Khane et al drawn to solution and solid-phase formation of glycosidic linkages, disclose the synthesis of oligosaccharides wherein a monosaccharide containing a hydroxyl group and covalently linked to a solid support is reacted with another monosaccharide containing an activated anomeric carbon to form an oligosaccharide (see figures 6-8). Additional examples are also disclosed with saccharide units having the azido group (see col. 63-65). These examples are similar to the instant saccharides.

Kovensky et al disclose the sulfation and hydrogenolysis reactions in solution phase (scheme 3, page 1569, steps m and n).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Khane and the reaction steps of Kovensky in a method to make glycosaminoglycans oligosaccharides involving the use of solid support with a reasonable amount of success since the methodological steps for the same are seen to be disclosed in the prior art. Even though Khane does not specifically use his method for the synthesis of glycosaminoglycans, one of ordinary skill in the art can readily recognize that the method of Khane lends itself to the synthesis of glycosaminoglycans especially since Khane has demonstrated the method with saccharides having the azido group. The sulfation and hydrogenolysis steps even though not disclosed by Khane, can still be used as instantly claimed based on the disclosure of Kovensky. Here again one of ordinary skill in the art would recognize that sulfating a hydroxyl or amino moiety and hydrogenolysis to remove a hydroxyl or amino protecting group are reactions that take place on groups attached to the saccharide unit and can be carried out even if the saccharide is covalently attached to a solid support since the covalent link is not the one affected in the said reactions.

One of ordinary skill in the art would be motivated to do so since the use of solid phase method for the synthesis of oligosaccharides makes isolation and purification unnecessary because excess reagents and decomposition products can simply be washed away from the resin bound product. This advantage translates into an enormous savings in terms of time, labor and cost (Khane, col. 6, lines 20-35).

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Conclusion

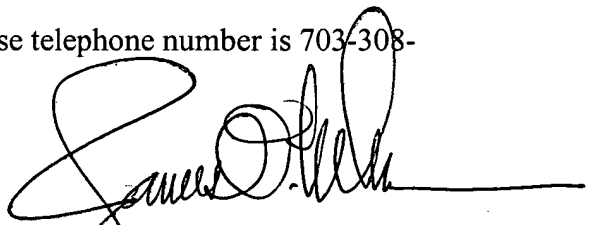
1. Claims 1-4, 10-12, 16-17 and 23-26 are rejected.
2. Claims 5 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
3. Claims 6-9 drawn to a trisaccharide with limitations on the substituents X, R and R' and claims 18-22 drawn to a method of preparing an oligosaccharide comprising reacting a uronic acid glycopyranosyl acceptor comprising especially a cyclic acetal at C1 and C2 appear to be free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
June 26, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600